

Nuclear Regulatory Commission

§ 32.15

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Except for electron tubes and ionization chamber smoke detectors and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) In the case of ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in §30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in §30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the

limits specified for that product in §30.15 of this chapter.

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998; 72 FR 58487, Oct. 16, 2007; 77 FR 43691, July 25, 2012]

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under §32.14 for products for which quality control procedures are required shall:

(1) Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions;

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in the license issued under §32.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded; and

(3) Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material must be considered a defective unit.

(b) No person licensed under §32.14 shall transfer to other persons for use under §30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under §32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria; or

(2) Any part or product contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (a)(2) of this section, unless:

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(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.14; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with the procedures specified in paragraphs (a)(2) and (b)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.14.

(c) [Reserved]

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: “CONTAINS RADIOACTIVE MATERIAL”;

(B) The name of the radionuclide (“americium-241” or “Am-241”) and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: “THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.”

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978; 72 FR 58487, Oct. 16, 2007; 73 FR 42673, July 23, 2008; 77 FR 43691, July 25, 2012]

§ 32.16 Certain items containing by-product material: Records and reports of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a